K011308

NOV 2 9 2001

SAFETY & EFFECTIVENESS DATA SUMMARY

Submitters Name, Address & Phone Number: Pajunk GmbH
Am Holzplatz 5-7
D-78187 Geisingen

Submission Correspondent: Lyle Howard Corporation
203 Main Street, PMB 166
Flemington, NJ 08822
Attention: Lynette Howard

Classification Name: Stimulator, Nerve, Peripheral
Common / Usual Name: Peripheral Nerve Stimulator
Proprietary Name: MultiStim

Establishment Registration Number: 9611612

Classification: Class II, Reg. # 868.2775

Performance Standards: Devices are manufactured according to EN-60-601-1, 93/42/EEC – European Medical Device Directive, EN 46001 / ISO 9001.

Substantial Equivalence: Peripheral Nerve Stimulators are currently being marketed and distributed by Fisher & Paykel Healthcare who currently holds a 510(k) #K953205.

Testing conducted to assure safety and effectiveness include but is not limited to:

Electrical Safety:	EN 60601-1-1, EN 601-2-10
Electromedical System:	EN 60601-1-1
Radioelectrical Disturbance:	EN 55011
Electromagnetic Capatibility:	EN 60601-1-2, EN 55011, EN 61000-4-2, IEC 801-3
Electrostatic Discharge Immunity Test:	IEC 1000-4-2
Routing Test Procedures:	EN 55022 & 11, EN 61000-4-2 pict. 5+6

Proposed devices have successfully met the requirements of the above.

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Description of the new device:

A peripheral nerve block is a subsection of regional anesthesia. The goal is to apply anesthesia for upper or lower limbs by means of blocking a nerve or a group of nerves innervating the segment in the extremities to be treated. So this anesthesia technique does impact the patient less than a general anesthesia and is indicated for operations in the upper and lower extremities and especially for patients with cardiac and/or pulmonary problems.

An important part of this technique is to find the target nerve to be blocked. This is typically done using insulated stimulation needles in conjunction with a nerve stimulator. The stimulator is connected to the stimulation needle and generates short impulses that transmit from the non-insulated tip of the stimulation needle to the patient. If applied close enough to the nerve, these pulses will overlay the "normal" information and cause the muscles innervated to contract in the frequency of the stimulation pulses. Using this techniques, the needle tip can be positioned close enough to the nerve, so when an anesthetic drug is injected, this will block the respective nerve.

The MultiStim devices are hand-held, battery-driven peripheral nerve stimulators for this purpose. There are two purposes that the device can be used for:

a) **for nerve finding with peripheral nerve stimulation needles**
b) **for relaxation monitoring in general anesthesia (VARIO-model only)**

In relaxation monitoring for general anesthesia, the peripheral nerve stimulation technique is used to interpret the muscular feedback to stimulation pulses applied through adhesive skin electrodes in regards to the level of muscle relaxing drugs in the patient. Special functions do support this. Due to the fact that the stimulation is done through the skin, much more electrical power is needed. That's why a stimulation current range of 0-60mA is needed.

In both applications, negative, monophasic pulses are to be generated by the devices and applied to humans either through peripheral nerve stimulation needles or through self-adhesive stimulation electrodes on the skin. Since the human body acts as a variable resistor and the anesthesiologist sets the device to a certain stimulation current, the nerve stimulator has to act as a constant current source. A built-in microprocessor constantly adapts the voltage applied to the patient in order to compensate the varying patient's resistance and to provide a constant current through the patient.

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The electrical current

The negative output of the nerve stimulator is connected to the stimulation needle. From the conductive tip of the stimulation needle there is a connection to the human body and to an adhesive skin electrode that acts as a ground and which is connected to the positive output of the stimulator again.

Intended Use:

The MultiStim VARIO is intended for use in both indications of anesthesiological nerve stimulation; firstly for percutaneous identification of peripheral nerves in conduction's anesthesia and secondly, for percutaneous stimulation in neuro-muscular monitoring in general anesthesia.

The MultiStim PLEX is intended for use as a nerve stimulator for plexus anesthesia and has the same functions as the MultiStim VARIO with the exception of the functions for percutaneous relaxation monitoring, the PAUSE function and adjustable stimulation impulse width.

Caution: Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Lynette Howard
Pajunk GmbH
203 Main Street
PMB 166
Flemington, NJ 08822

Re: K011308
MultiStim Nerve Stimulator
Regulation Number: 868.2775
Regulation Name: Electrical Peripheral Nerve Stimulator
Regulatory Class: II (two)
Product Code: BXN
Dated: August 30, 2001
Received: August 31, 2001

Dear Ms. Howard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INTENDED USE STATEMENT

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Division of Cardiovascular & Respiratory Devices
510(k) Number K011308

Prescription Use ✓
(Per 21 CFR 801.109)